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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

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MEMORANDUM

February 10, 2015

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Full Committee Markup of H.R. 734, the "Federal Communications Commission Consolidated Reporting Act of 2015;" H.R. 639, the "Improving Regulatory Transparency for New Medical Therapies Act;" H.R. 471, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015;" H.R. 647, the "Access to Life-Saving Trauma Care for All Americans Act;" H.R. 648, the "Trauma Systems and Regionalization of Emergency Care Reauthorization Act;" and, H.R. 212, the "Drinking Water Protection Act."

On Wednesday, February 11, 2015, at 5:00 p.m. in room 2123 of the Rayburn House Office Building, the full Committee on Energy and Commerce will conduct opening statements for the markup of H.R. 734, the "Federal Communications Commission Consolidated Reporting Act of 2015;" H.R. 639, the "Improving Regulatory Transparency for New Medical Therapies Act;" H.R. 471, the "Ensuring Patient Access and Effective Drug Enforcement Act of 2015;" H.R. 647, the "Access to Life-Saving Trauma Care for All Americans Act;" H.R. 648, the "Trauma Systems and Regionalization of Emergency Care Reauthorization Act;" and, H.R. 212, the "Drinking Water Protection Act." The Committee will reconvene on Thursday, February 12, at 10:00 a.m. in 2123 Rayburn House Office Building.

I. H.R. 734, THE FEDERAL COMMUNICATIONS COMMISSION CONSOLIDATED REPORTING ACT OF 2015

On February 2, 2015, Chairman Walden circulated a discussion draft of the Federal Communications Commission Consolidated Reporting Act of 2015. The discussion draft would consolidate eight statutorily mandated FCC reports into a single biennial report on communications marketplace competition. The FCC would be required to outline the agency's agenda for the coming two years to address marketplace barriers and the actions taken in the previous two years to address barriers identified in the last report. The draft bill would further

eliminate additional references in the Communications Act to certain outdated reports. Many are one-time reports that Congress requested by law, rather than ongoing data collection or analysis.

On February 4, 2015, the Subcommittee on Communications and Technology met to consider the discussion draft. Mr. Scalise and Ms. Eshoo offered a manager's amendment to preserve the requirement that the FCC report on how retransmission consent fees impact consumer cable rates and clarify that nothing in the bill alters the FCC's authority under Section 706 of the Telecommunications Act of 1996. The amendment was adopted and the bill was favorably forwarded to the full Committee, as amended, by a voice vote.

II. H.R. 639, IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

This bill would require the DEA to place a drug or substance into the controlled substances schedule recommended by the Food and Drug Administration (FDA) within 45 days of receiving the FDA recommendation. It also would require DEA to make final decisions on registration applications to manufacture or distribute a controlled substance to be used only in connection with a clinical trial within 180 days.

Last Congress, the bill, as H.R. 4299, passed the Committee by voice vote on June 10, 2014, and the Judiciary Committee on Sept. 10, 2014. It was placed on the Union Calendar on Sept. 19, 2014, but was never brought to the House floor.

On February 4, 2015, the Subcommittee on Health met to consider four public health bills, including H.R. 639. Mr. Pitts offered an amendment in the nature of a substitute to H.R. 639 which was adopted by a voice vote. H.R. 639 was favorably forwarded to the full Committee, as amended, by a voice vote.

An amendment in the nature of a substitute will be offered at the full Committee markup, incorporating technical assistance from FDA and DEA.

III. H.R. 471, ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT

This bill, authored in the previous Congress, by Reps. Blackburn, Marino, Welch and Chu, would define Controlled Substances Act phrases, "consistent with the public health and safety" and "imminent danger." It also would require the Drug Enforcement Administration (DEA) to permit registrants to submit an action plan to remedy statutory and regulatory violations severe enough that DEA is considering revoking or suspending the registrant's controlled substances license. It would also require the Food & Drug Administration (FDA), in consultation with DEA, to submit a report to Congress one year after enactment regarding patient access to controlled substances medicines. Additional topics of coverage within the report are to include efforts to benefit patients and prevent diversion and abuse of controlled substances.

The bill, as H.R. 4709, passed the Committee by voice vote on June 10, 2014, and passed the House by voice vote under suspension of the rules on July 29, 2014. On February 4, 2015, the Subcommittee on Health favorably forwarded H.R. 471 to the full Committee by a voice vote.

It is possible that a manager's amendment will be offered at the full Committee markup, incorporating technical assistance from FDA and DEA.

IV. H.R. 648, TRAUMA SYSTEMS AND REGIONALIZATION OF EMERGENCY CARE REAUTHORIZATION ACT

The Trauma Systems and Regionalization of Emergency Care Reauthorization Act, sponsored by Congressman Green and Congressman Burgess, reauthorizes four trauma programs which were established or reauthorized in the Affordable Care Act.[1] This legislation reauthorizes the programs, detailed below, at $24 million per year, from FY 2015 through FY 2020, and makes a number of technical changes. None of these trauma programs have been funded, however, in recent years.

- Section 1202 of the Public Health Service Act authorizes a competitive grant program for improving trauma care in rural areas. This program permits the Secretary of Health and Human Services (HHS) to make grants to public and nonprofit private entities for the purposes of conducting research and establishing demonstration projects to improve the availability and quality of emergency medical services in rural areas.

- Section 1203 of the Public Health Service Act authorizes a competitive grant program for improving or enhancing the development of trauma care systems. This program received federal funding from 1992-1994 and 2001-2005. During that time, grants were awarded to all 50 states, the District of Columbia, and the territories for activities such as designating a state agency to lead the administration of a trauma system; developing plans for state and regional trauma systems; and training emergency medical services personnel in trauma assessment and triage protocols.[2]

- Section 1204 of the Public Health Service Act authorizes a competitive grant program for regionalized systems for emergency care and trauma response. This program directs the Secretary of HHS to award grants and contracts to states, partnerships of one or more states and one or more local governments, Indian tribes, or partnerships of one or more Indian tribes to establish pilot projects to design, implement, and evaluate regionalized emergency care and trauma models.

- Part B of title XII of the Public Health Service Act authorizes formula grants to states in order to improve access to high-quality trauma care. When these programs were last funded, states and territories used the funds to develop, implement, and monitor modifications to the trauma care component of the state plan for the provision of emergency medical services.

During the 113th Congress, similar legislation (H.R.4080), passed the Committee by voice vote on April 3, 2014, and passed the House of Representatives on June 24, 2014. On February 4, 2015, the Subcommittee on Health favorably forwarded H.R. 648 to the full Committee by a voice vote.

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[1] The Affordable Care Act consists of two public health laws, Pub. L. No. 111-148 and Pub. L. No. 111-152.

[2] Health Resources and Services Administration, *Trauma-EMS Systems Program Report FY 2001-FY 2005* (online at ask.hrsa.gov/detail_materials.cfm?ProdID=3752).

V. H.R. 647, ACCESS TO LIFE-SAVING TRAUMA CARE FOR ALL AMERICANS ACT

The Access to Life-Saving Trauma Care for All Americans Act, sponsored by Congressman Burgess and Congressman Green, reauthorizes additional trauma programs that are set to expire in FY 2015.

Part D of title XII of the Public Health Service Act authorizes grant programs to trauma centers to assist with uncompensated care costs; advances centers' core missions by supporting patient stabilization and transfer, education and outreach, coordination with other trauma systems, and essential personnel and services; and provide emergency funds to centers at risk of closing or reducing services. These programs were reauthorized in the ACA at a funding level of $100 million per year, but have not received funding.

Part H of title XII of the Public Health Service Act authorizes grants to states to improve the availability of trauma center care services and trauma-related physician specialties. The program was first authorized in the ACA at $100 million per year, but has also never been funded.

The Access to Life-Saving Trauma Care for All Americans Act reauthorizes these programs at their currently-authorized funding levels for FY 2016 through FY 2020. H.R. 647 also moves the programs under part D and part H of title XII of the Public Health Service Act to the Office of the Assistant Secretary for Preparedness (ASPR), and makes a number of technical changes.

On February 4, 2015, the Subcommittee on Health favorably forwarded H.R. 647 to the full Committee by a voice vote.

VI. H.R. 212, DRINKING WATER PROTECTION ACT

H.R. 212, the "Drinking Water Protection Act" was introduced on January 8, 2015 by Rep. Bob Latta (R-OH) and cosponsors including Rep. Marcy Kaptur (D-OH). The bill was developed in response to a drinking water contamination event in Lake Erie in August 2014 that resulted in a "do not drink" order for the city of Toledo. The contaminants involved in the Toledo event were microcystins, one type of algal toxin.

The Committee Print of H.R. 212 would amend the Safe Drinking Water Act to require EPA to develop a strategic plan for assessing and managing the risks posed by algal toxins in drinking water. Harmful algal blooms cause significant harm to marine and aquatic ecosystems, coastal communities and human health. Some harmful algae produce toxins, including cyanotoxins, which can contaminate public water supplies. Blooms have been doubling in

occurrence every decade since the mid-1900s[3] and anthropogenic nutrient enrichment and global climate change are thought to be fueling events of increased frequency, size and intensity.[4]

The strategic plan developed pursuant to the legislation will include steps and timelines for evaluating health risks from algal toxins, establishing a list of potentially harmful algal toxins, summarizing the health effects and the factors that encourage algal growth, determining whether to issue public health advisories and publish guidance regarding detection and monitoring methods, and recommending feasible treatment options. The bill also requires the Comptroller General to prepare and submit a report to Congress on funding over the last four fiscal years to address risks from cyanotoxins. The bill does not provide funding to prepare or implement the plan.

H.R. 212 was the subject of a legislative hearing and markup in the Subcommittee on Environment and the Economy on February 5, 2015. Several changes sought by Democratic members were adopted in the amendment in the nature of a substitute offered by Mr. Shimkus during that markup. The changes broadened the scope of the strategic plan to cover all algal toxins, ensure that all toxins that may have an adverse effect on human health would be included, and explicitly included sourcewater protection measures among possible treatment options. An amendment offered by Mr. Tonko to authorize funds to implement the bill was not adopted. The bill was favorably forwarded to the full Committee, as amended, by a voice vote.

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[3] A. H. Altieri and K.B. Gedan, *Climate change and dead zones*, Global Change Biology (Nov. 10, 2014).

[4] *Id.*; R.J. Gowen et al., *Anthropogenic nutrient enrichment and blooms of harmful phytoplankton*, Oceanography and Marine Biology: An Annual Review, Vol. 50 (2012).